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Review Article

Human amniotic membrane as a dural substitute in neurosurgery: A systematic review

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Received : 30 August 2022
Accepted : 06 October 2022
Published : 04 November 2022

DOI
10.25259/SNI_794_2022

Quick Response Code:

ABSTRACT

Background: Several studies have highlighted the use of human amniotic membrane (HAM) in neurosurgical procedures as an effective dural substitute. HAM has inherent antifibrotic and anti-inflammatory properties and exhibits immunomodulatory effect that makes it an ideal dural substitute. Other advantages including easy availability, low cost of procurement, and storage also render it a promising dural substitute especially in low- and middle-income countries.

Methods: A systematic literature search was performed using PubMed, Scopus, and Google Scholar databases, using the search terms "human amniotic membrane," "dural repair," and "neurosurgery." To be eligible for inclusion in our review, papers had to report primary data, be published in English language and report dural repair on humans with human amniotic membrane. Eligibility assessment was conducted by two independent reviewers with qualitative analysis on the basis of surgical utility, postoperative complications, and histological analysis.

Results: Eight articles met the predefined inclusion criteria, including three randomized control trials and five cohort studies. We evaluated the use of HAM grafts in dural repair for elective cranial surgery (four studies), trauma surgery (three studies), and elective spine surgery (one study). Cases with postoperative cerebrospinal fluid (CSF) leak were reported by two studies. Other postoperative complications including meningitis, hydrocephalus, pseudomeningocele, CSF collection in subdural space, and subacute subdural hematoma were reported by one study each. Postsurgical histological analysis was reported by three studies highlighting the antiadhesive and integrative properties of HAM.

Conclusion: The current review of evidence suggests that in terms of postsurgical outcomes, HAM is comparable with commercially available dural substitutes.

Keywords: Amnion, Dural repair, Dural substitute, Duraplasty, Human amniotic membrane

INTRODUCTION

Human amniotic membrane (HAM) was first used for therapeutic purposes was for skin transplantation in 1910.[15] Several surgical specialties such as ophthalmology, dermatology, plastic surgery, urology, and otolaryngology have reported using HAM for a variety of purposes.[12,21] The rapid acceptance of its use can be explained by its characteristic antifibrotic and anti-inflammatory nature and its immunomodulatory effect. The surface epithelial cells of HAM do not express

antigens of histocompatibility such as human leukocyte antigen A, B, C, or DR, or B2-microglobulin which results in the membrane never being rejected by recipient tissue.[1] This valuable immunosuppressive characteristic of amniotic membrane transplantation has played a key role in its success across different surgical fields.[13] The antifibrotic effect can be explained by the suppressed expression of tissue growth factors signaling and their receptors, leading to decreased fibroblast proliferation and differentiation.[18] HAM expresses its anti-inflammatory properties by inhibition of proteinase activity and pro-inflammatory cytokines such as interleukin (IL)-1a and IL-B.[10] The multimodal utility of HAM makes it an ideal choice for graft material in various surgical fields.

For neurosurgery in particular, several studies have shown its usefulness as a substitute for dural repair in both cranial and spine surgeries.[5,15,23] Biological tissue (allograft, xenograft, and autograft) and synthetic materials have been already validated as competent dural grafts.[4] Biological autografts are preferred whenever available, particularly with pericranial grafts which do not require an additional incision for graft harvesting. Synthetic grafts, although easy to use, are expensive. In low- and middle-income countries, certain characteristics of HAM grafts, including easy availability, low cost of procurement, and storage, make it a favorable dural substitute.[9] However, ethical concerns and preservation requirements associated with human tissue donation have limited its use in clinical practice and commercial availability in many countries.[11]

Due to its similarities to the dura mater and its immunosuppressive effect, HAM has been considered a suitable substitute for dura. With this systematic review, we aim to establish the clinical applications of HAM grafts in dural repair in neurosurgery as a successful and robust dural substitute, with comparisons to already well-known dural graft materials.

MATERIALS AND METHODS

A literature search was performed using PubMed, Scopus, and Google Scholar databases after a predefined search strategy. This combined three search terms, "human amniotic membrane," "dural repair," and "neurosurgery," with Boolean operators "AND" and "OR." As a result, our search strategy was (((Human Amniotic Membrane) OR (Amniotic membrane) OR (HAM) OR (Amnion)) AND ((Dural repair) OR (Duraplasty) OR (Dural substitute)) AND ((Neurosurgery) OR (Craniectomy) OR (Craniotomy) OR (Meningioma) OR (posterior fossa tumor) OR (brain tumor) OR (spine tumor) OR (neuro-oncology) OR (Brain surgery) OR (Spine surgery))). To be eligible for inclusion in our review, papers had to report primary data, be published in English and report dural repair on humans with HAM.

An initial title screen was independently done by two neurosurgical experts (Reviewer 1 [Z.S.]) and Reviewer 2 [H.B.]) followed by an independent review of abstracts. Full articles were reviewed where ambiguity regarding eligibility remained and discussed with a third arbiter (S.B.).

The selected articles were reviewed and data describing the authors of the study, year of publication, type of study, total number of patients, demographics of patients, presented pathology, type of neurosurgical procedure, number of patients with HAM dural repair, number of patients with synthetic and biological dural repair, and outcomes of procedure were extracted. Due to a paucity of comparative data between cohorts, meta-analysis was not possible. Qualitative assessment was conducted using the NIH Quality Assessment Tool for Case Series Studies and randomized control trials (RCTs) using the Cochrane Risk of Bias (RoB 2) assessment tool [Table 1].

RESULTS

From a total of 561 articles identified from the original search algorithm, eight were identified which met all inclusion criteria for incorporation in our subjective analysis. Figure 1 highlights the study selection process from this systematic review, as according to the PRISMA statement criteria.

Risk of bias assessment

Three studies were reported as good quality studies and two reported as fair quality according to the NIH Quality Assessment Tool for Case Series Studies [Table 1a]. Concerns were present regarding the comparability of enrolled patients as well as whether cases included were consecutive on not. According to the Cochrane RoB2 assessment tool [Table 1b], all three clinical trial studies were reported as having a low risk of bias, scoring well in all categories.

HAM as a dural substitute in trauma neurosurgery

Fauzi *et al*. from Indonesia reported their experience of using HAM in eight patients who underwent cranioplasty after decompressive craniectomy. The article did not report demographic details of the patients nor the pathologies with which they had presented. The authors observed no cases of postoperative cerebrospinal fluid (CSF) leak in their series. Postsurgical histological analysis showed adequate fibrocyte infiltration.[8] Turchan *et al*. from Indonesia compared HAM as a dural substitute with autologous temporal fascia in patients undergoing decompressive craniectomy followed by histological analysis of tissue sampled at the time of cranioplasty. Result of eight patients was reported and none of the patients had a postoperative CSF leak. The histological analysis revealed that the fibrocyte infiltration of the HAM graft group was not significantly different from

Table 1a: Quality assessment using (a) NIH quality assessment tool for case series studies.

	Tomita *et al.*, 2012	Fauzi *et al.*, 2017	Marton *et al.*, 2018	Eichberg *et al.*, 2018	Eichberg *et al.*, 2019
1. Was the study question or objective clearly stated?	✓	✓	✓	✓	✓
2. Was the study population clearly and fully described, including a case definition?	✓	✓	✓	✓	✓
3. Were the cases consecutive?	X	X	X	✓	✓
4. Were the subjects comparable?	X	✓	✓	X	
5. Was the intervention clearly described?	✓	✓	✓	✓	✓
6. Were the outcome measures clearly defined, valid, reliable, and implemented consistently across all study participants?	✓	X	✓	✓	✓
7. Was the length of follow-up adequate?	✓	X	✓	✓	✓
8. Were the statistical methods well-described?	n/a	n/a	n/a	n/a	n/a
9. Were the results well-described?	✓	✓	✓	✓	✓
10. Overall rating	Fair (6/9)	Fair (5/9)	Good (7/9)	Good (7/9)	Good (8/9)

Table 1b: Quality assessment using (b) the Cochrane Risk of Bias 2 assessment tool.

	Turchan *et al.* 2018	Tahami *et al.* 2019	Marton *et al.* 2021
Randomization process	Low risk	Unclear	Low risk
Deviations from intended interventions	Low risk	Low risk	Low risk
Missing outcome data	Low risk	Low risk	Low risk
Measurement of the outcome	Low risk	Low risk	Low risk
Selection of the reported result	Low risk	Low risk	Low risk
Overall	Low risk	Low risk	Low risk

the temporal fascia graft group showing that healing of dural defect in the HAM group was as adequate as the fascial graft group.[24] A RCT was conducted in Italy by Marton *et al.* on patients who underwent decompressive craniectomy followed by cranioplasty with HAM and biological dural substitutes. Of the 25 patients in whom HAM was used, one patient experienced a subacute subdural hematoma after cranioplasty, three patients developed CSF collection in the subdural space, and one patient developed a CSF leak. Microscopic analysis revealed complete integration of HAM to the autologous dura and development of thick plates of dense fibrous tissue with small reactive vessels, reactive fibroblasts, and lymphocyte infiltrates[16] [Tables 2 and 3].

HAM as a dural substitute in elective cranial neurosurgery

Tomita *et al.* from Japan published the very first study reporting HAM as a dural substitute in 2012. They used HAM in a cohort of 10 patients who underwent surgery for skull base brain tumors, including meningioma (five), chondrosarcoma (two), chordoma (one), cavernoma (one), and craniopharyngioma (one). Half of the patients were male and the average age of the patients was 54.9 with their age ranging from 5 to 71 years. None of their patients developed postoperative CSF leak or experienced any other adverse reactions.[23] Eichberg *et al.* from the USA presented the largest study reporting HAM as a dural substitute. The study included 155 cases with a range of pathologies including various brain tumors (112), metastasis (34), colloid cysts (three), encephalitis (two), and others. Of the 155 patients, 122 underwent craniotomy, 32 underwent transsphenoidal surgery, and one underwent a combined craniotomy and transnasal endoscopy with a HAM allograft to augment dural closure. Only one postoperative complication was reported which was a superficial surgical site infection and required a wash out without a craniotomy. However, no CSF leaks were reported.[6] Eichberg *et al.* retrospectively reviewed 120 cases in whom HAM was utilized to supplement sellar closure during transsphenoidal endoscopic endonasal surgery for resection of pituitary adenomas. The authors reported two cases of postoperative CSF leak and no cases of meningitis.[7] Tahami *et al.* from Iran compared the results of dural repair using HAM with pericranium as a dural graft in 60 patients undergoing craniotomy. The study reported two cases of pseudomeningocele, nine cases of hydrocephalus, one case of meningitis, and no cases of CSF leak among HAM group[22] [Tables 2 and 3].

HAM as a dural substitute in spine surgery

Marton *et al.* from Italy reported their experience with HAM as a dural substitute in five neonates who underwent spinal dysraphism repair including three neonates diagnosed with myelomeningocele and two diagnosed with lipomeningocele. The authors reported no postoperative complications among the neonates.[17]

In Table 4, we have summarized the number of cases of postoperative complications as a percentage of the total

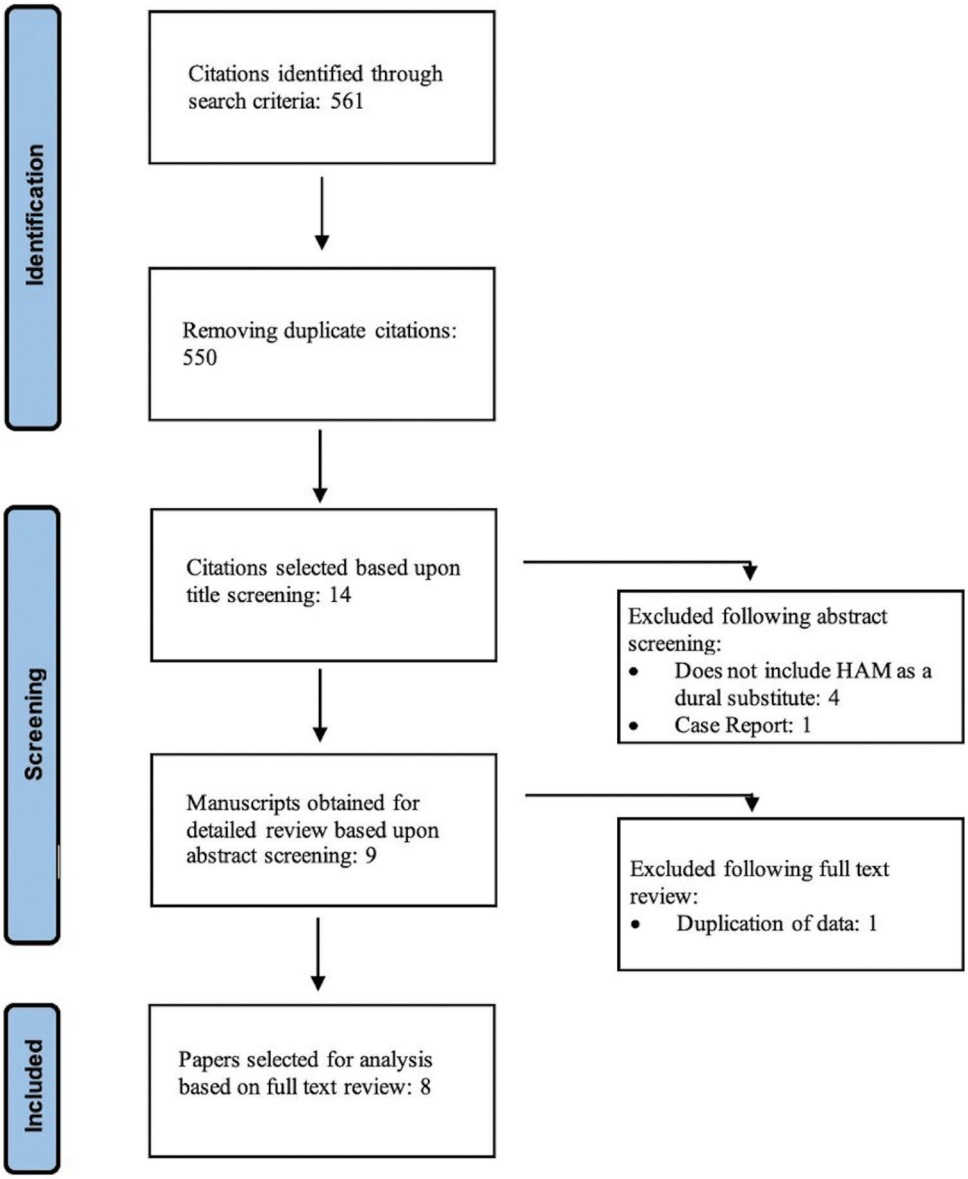

Figure 1: Study selection process according to the PRISMA statement criteria.

number of patients who underwent dural repair with HAM from all included articles. Hydrocephalus was the most commonly reported postoperative complication in 9% of patients whereas no adverse reactions or CSF leak was reported.

DISCUSSION

In this systematic review, we report postoperative clinical outcomes associated with dural repair utilizing HAM as a dural substitute, including the frequency of CSF leak, subdural CSF collection, pseudomeningocele, hydrocephalus, meningitis, and adverse reactions reported in the current literature. We have also reported the existing literature on histological changes following dural repair using HAM as a dural substitute. Although to date, there is a limited literature on the topic with very few studies looking at long-term histological changes or long-term clinical outcomes, review of literature clearly shows HAM as a dural substitute to be comparable with clinical outcomes of dural repair using other biological or synthetic substitutes.

Several neurosurgical conditions require some form of a dural substitute to cover the exposed brain, including resection of dural-based lesions, trauma, expansile duroplasty, and posterior fossa surgeries. This step of the neurosurgical procedure helps in decreasing the incidence of CSF leak, preventing infections, and is also beneficial when performing

Table 2: Patient demographics and clinical presentation.

Authors	Country	Patients in control group	Patients with HAM dural repair (*n*)	Gender (*n*) M: (%) F: (%)	Mean age in years (range)	Indication for surgery (*n*)
Tomita *et al.*[23]	Japan	-	10	5 (50%) 5 (50%)	54.9 (5–71)	Primary brain tumors 10; chondrosarcoma 2, chordoma 1, cavernoma 1, craniopharyngioma 1, meningioma 5
Fauzi *et al.*[8]	Indonesia	-	8	-	-	-
Turchan *et al.*[24]	Indonesia	8 (temporalis fascia)	8	6 (75%) 2 (25%)	33	TBI with SDH and ICH: 6 Stroke with ICH: 3 TBI with SDH: 2
Marton *et al.*[17]	Italy	-	5	3 (60%) 2 (40%)	Neonates	MMC: 3 LMC: 2
Eichberg *et al.*[7]	USA	-	155	61 (39.4%) 94 (60.6%)	57.2 (19–91)	Brain tumor: 112 Metastasis: 34 Colloid cyst: 3 Encephalitis: 2 Aneurysmal bone cyst: 1 cavernous Malformation: 1 epidermoid cyst: 1, hemorrhagic Lesion of nondiagnostic pathology: 1
Eichberg *et al.*[6]	USA	-	120	54 (45%) 66 (55%)	53.5 (20–89)	Pituitary adenoma: 120
Tahami *et al.*[22]	Iran	30 (pericranium autograft)	30	17 (68%) 13 (32%)	43.9 (5–80)	-
Marton *et al.*[16]	Italy	25 (biological dural grafts)	25	15 (60%) 10 (40%)	- (26–80)	Refractory malignant HTN due to: ischemic stroke: 11 Acute SDH and cerebral edema: 9 IPH: 4 EDH and cerebral contusions: 1

Table 3: Surgical procedures and significant outcomes in HAM patients.

Authors	Neurosurgical procedure	Postoperative complications	Postoperative histological analysis
Tomita *et al.*[23]	Skull base surgery: 10	CSF leak: 0 Adverse reactions: 0	-
Fauzi *et al.*[8]	Decompressive craniectomy followed by cranioplasty: 8	CSF leak: 0	Adequate fibrocyte infiltration
Turchan *et al.*[24]	Decompressive craniectomy followed by cranioplasty: 8	CSF leak: 0	Adequate fibrocyte infiltration
Marton *et al.*[17]	Spinal dysraphism repair: 5	Adverse reactions: 0	-
Eichberg *et al.*[7]	Craniotomy: 122 Transsphenoidal: 32 Combined craniotomy and transnasal endoscopic: 1	CSF leak: 0 Superficial wound infection: 1	-
Eichberg *et al.*[6]]	Transsphenoidal endoscopic endonasal surgery: 120	CSF leak: 2 Meningitis: 0	-
Tahami *et al.*[22]	Craniotomy: 30	CSF leak: 0 Hydrocephalus: 9 Pseudomeningocele: 2 Meningitis: 1	-
Marton *et al.*[16]	Decompressive craniectomy followed by cranioplasty: 25	CSF collection in subdural space: 3 CSF leak: 1 Subacute subdural hematoma: 1	Complete integration of the HAM to the autologous dura Development of thick plates of dense fibrous tissue with small reactive vessels, reactive fibroblasts, and lymphocyte infiltrate

CSF: Cerebrospinal fluid, HAM: Human amniotic membrane

Table 4: Summarized postoperative complications.

Postoperative complications in patients with HAM dural repair (*n*=361)	Total cases % (*n*)
Adverse reactions	0.0 (0)
Cerebrospinal fluid leak	0.0 (0)
Hydrocephalus	2.5 (9)
Meningitis	0.3 (1)
Pseudomeningocele	0.6 (2)
Subacute subdural hematoma	0.3 (1)
Superficial wound infection	0.3 (1)

HAM: Human amniotic membrane

a second surgery in avoiding cortical injury.[2] Dural repair, whether elective or emergency, cranial, or spinal, regardless of the type of material used, carries a risk of potential postoperative complications such as CSF leak, infections, pseudomeningocele formation, and scarring.[3,8] Four types of dural substitutes are commonly used: autograft, allograft, xenograft, and synthetic grafts. An ideal dural substitute should possess certain features including tensile strength, elasticity, ease of handling, minimum anti-genetic properties, availability, and affordability. There are several advantages of using autograft. Pericranium or temporal fascia, for example, they do not induce an immunological or inflammatory reaction, are nontoxic, strong, and inexpensive.[20] However, pericranium can be damaged during harvesting or be insufficient for a large dural defect, whereas autologous temporal fascia of fascia lata requires an additional incision, leading to increased operating time.[14,20] As a result, various synthetic and biological substitutes are commonly used in dural repair.[19] HAM grafting has been used in various surgical fields since 1910, although its use in neurosurgery as a dural substitute was not reported till more than a century later.[15] In 2012, Tomita *et al*. reported the first ever use of HAM as a dural substitute in humans after which subsequent studies evaluating HAM as a dural substitute have also reported favorable characteristics of HAM for dural repair.[23]

Turchan *et al*. compared HAM with temporalis muscle fascia as a dural substitute in patients who underwent decompressive craniectomy followed by duraplasty. The author reported HAM to be comparable with temporal fascia and was able to provide watertight dural closure with no CSF leak.[24] Tahami *et al*. compared the results of HAM as a dural graft and pericranium dural graft in terms of CSF leakage and pseudomeningocele formation. The authors reported no significant difference between the two groups in any complication including CSF leak, meningitis, hydrocephalus, and formation of pseudomeningocele.[22] The former two studies represent HAM as a favorable dural substitute compared to two of the most commonly used autologous dural substitutes. Along with its immunosuppressive effect and comparable postoperative complications with autologous tissues, HAM can be available in larger grafts size, tackling the issue of unavailability of large harvests of autologous dural grafts. At present, HAM has not been compared to a synthetic dural substitute in a RCT. Although, synthetic grafts and HAM share the advantages of ready availability and can be cut into any shape particularly in larger sizes, synthetic grafts can release growth factors resulting in scarring along with suture fusion whereas HAM is known to have an antifibrotic effect, leading to suppressed scarring. Nonetheless, RCTs comparing synthetic grafts to HAM as a dural repair are required to identify differences in terms of intra- and post-operative outcomes in dural repair surgeries.

Several studies have reported on the clinical outcomes in patients in whom HAM is utilized as a dural substitute including CSF leak, CSF collection in subdural space, pseudomeningocele, hydrocephalus, meningitis, and adverse reactions.[6-8,16,17,22-24] However, examining the antiadhesive properties and integration into native tissue is equally important when evaluating a dural substitute. Amniotic membrane has inherent anti-inflammatory properties reducing subsequent adhesions, inhibiting vascularization, and promoting epithelialization.[16] Turchan *et al*. reported histological changes and reported that the fibrocyte infiltration thickness of the HAM graft group was not significantly different from the temporal fascial graft group showing that microscopic fibrocyte infiltration for dural defect healing in the HAM group was as adequate as the fascial graft group.[24] Marton *et al*.'s microscopical analysis revealed complete integration of the HAM to the autologous dura and development of thick plates of dense fibrous tissue with small reactive vessels, reactive fibroblasts, and lymphocytes infiltrate; highlighting the antiadhesive properties and pluripotential properties of HAM.[16] Marton *et al*.'s study displayed the antiadhesive characteristic of HAM as follow-up, magnetic resonance imaging scans of neonates who underwent spinal dysraphism repair showed a satisfying detethering of the spinal cord with no obvious evidence of new adherence formation.[17] In addition, Fauzi *et al*.'s histological review highlighted amniotic membrane's ability to stimulate adequate fibrocyte infiltration allowing healing of the dura.[8]

Limitations

The substrate population was variable in the studies included in this review and the data were nonuniformly presented, so we could not perform a meta-analysis. Of the eight studies included in this review, only three were RCTs, and the largest sample size was 60, which limits the generalizability of these results. Although we present our review on all neurosurgical procedures, only one study reports HAM utilized as a dural substitute in spine surgery. There is a need of further studies with larger sample sizes, to evaluate HAM as a dural substitute in cranial and spine surgeries to better understand the qualities of this relatively novel dural substitute.

CONCLUSION

HAM grafting can be routinely integrated into neurosurgical procedures. Studies have shown favorable results in patients undergoing dural repair in cranial and spine surgeries with HAM. Postoperative outcomes including CSF leaks, infections, and adverse reactions in patients with amniotic membrane dural repair have shown to be comparable with currently used dural materials.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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How to cite this article: Shah Z, Bakhshi SK, Bajwa MH, Khalil M, Dewan MC, Shamim SM. Human amniotic membrane as a dural substitute in neurosurgery: A systematic review. Surg Neurol Int 2022;13:505.